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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,035	09/22/2003	Dominic P. Behan	AREN-005CON (5.US10.CON)	2177

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Arena Pharmaceuticals, Inc.
Bozicevic, Field & Francis LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,035	BEHAN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-10,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8-10, 20, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 07/23/2008 has been entered. Claims 1-3, 8-10, 20, and 21 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 8, 9, and 20 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,653,086 is withdrawn.

The rejection of claims 1-3, 8-10 and 20 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicants' argument.

Claim Rejections under 35 USC § 101 and 112, 1st paragraph

(i). 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claims 1-3, 8-10, 20, and 21 are rejected under 35 U.S.C. 101 and 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The basis for the rejection is set forth in the previous office action.

(iii). Response to Applicants' argument

Beginning at page 8, the 4th paragraph of Applicants response, Applicants argue that the utility of the claimed invention is similar to the utility of PCR. Applicants argue that the utility of the presently claimed invention is not derived from the specific identity and utility of the constitutively active orphan GPCR employed in the method, rather from the ability of a user to employ the claimed methods to identify agonist/inverse agonist compounds for virtually any constitutively active orphan GPCR that is of interest to them.

Applicants' argument has been fully considered, but is not deemed to be persuasive for because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

Claims 1-3, 8-10, 20, and 21 are drawn to a method for directly identifying an agonist or inverse agonist of an endogenous, constitutively active G protein coupled orphan receptor using a GPCR fusion protein comprising an endogenous, constitutively active G protein coupled orphan receptor and a G protein, The utility analysis for the claimed methods is based upon the utility of the agonists and antagonists screened by the method. Since neither the prior art nor the specification discloses the biological functions or physiological significance of the orphan G protein coupled receptors, the

agonists and antagonists do not have a specific and substantial utility. Consequently the claimed method does not have a patentable utility.

Moreover, unlike PCR technology, the instant claims are drawn to "a method of screening", not a tool for studying and monitoring any particular diseases. According to MPEP, even if screening assays have a clear, specifc and unquestionable utility in analyzing compounds in a research setting, this utility does not represent a utility in a patent sense. In fact, MPEP 2107.01 clearly states that a method of assaying for or identifying a material that itself has no specific and/or substantial utility does not have a specific and/or substantial utility.

For the reasons above and the reasons set forth in the previous office action mailed on 01/24/2008, the rejections under 35 U.S.C. 101 and 112, first paragraph.

Claim Rejections under 35 U.S.C. 103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). Claims 1-3, 8-10 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert et al (IDS, Ref., J. Biol.. Chem, 1998, Vol 273, No. 9, pages

5109-5116 in view of Scheer et al (IDS, Ref., J. of receptor and Signal Transduction Research, 1997, Vol 17, pages 57-73) and further in view of Song et al (IDS, Ref., Genomic 1996, Vol.28, pages 347-349), Bertin et al (IDS, Ref., Proc. Natl. Acad. Sci. USA, 1994, Vol.91, pages 8827-8831) and Wise et al (IDS, Ref., J. Biol. Chem, 1997, Vol 272, No. 39, page 24673-24678). The basis for the rejection is set forth in the previous office action.

(iii). Response to Applicants' argument

Beginning at page 8, the 4th paragraph of Applicants response, Applicants argue that Seifert et al. fail to teach or even suggest that the claimed methods wherein the constitutively active G protein coupled receptor is an orphan receptor. Applicants argue that also fails to teach or suggest the final candidate identification step recited in the claims as amended. Applicants argue that Siefert et al. employ known agonists and inverse agonists of the GPCR. Applicants also criticize other cited references separately.

Applicants' argument has been fully considered, but is not deemed to be persuasive for because it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the method of Seifert et al. to identify an agonist or inverse agonist of an endogenous, constitutively active orphan G protein coupled receptor, such as GPR6 taught by Song et al. with a reasonable expectation of success. One would have been motivated to do so because the constitutively active G protein

coupled receptor can be used to identify an agonist or inverse agonist without the need of a known ligand as shown by Seifert et al.

Claim Rejections under Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 10, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,653,086. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-3, 10, and 20 of the instant application are drawn to a method for directly identifying an agonist or inverse agonist of an endogenous, constitutively active G protein coupled orphan receptor using a GPCR fusion protein comprising an endogenous, constitutively active G protein coupled orphan receptor and a G protein, whereas claims 1-3 of U.S. Patent No. 6,653,086 is drawn to the same method except that a GPCR fusion protein comprising an endogenous, constitutively active G protein coupled orphan receptor and a Gsα protein. Therefore, the patented claims are related

to the instant claims as species to genus with respect to G protein. A patented species (an endogenous, constitutively active G protein coupled orphan receptor and a Gsα protein) renders its genus (a GPCR fusion protein comprising an endogenous, constitutively active G protein coupled orphan receptor and a G protein) obvious and thus anticipates the genus.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
December 11, 2008